

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

<h1 style="margin:0;">FSIS NOTICE</h1>	37-01	9/5/01
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**MAKING DETERMINATIONS ABOUT WHETHER PRODUCT IS PRODUCED
OR SHIPPED UNDER PART 417 HACCP REGULATIONS**

1. What is the purpose of this Notice?

This notice is designed to provide clarification about the meaning of “produced or shipped” as used in part 417 HACCP regulations. The need for such clarification was brought to FSIS’ attention by a petition from several industry organizations, dated 12/30/99. The petition included a request to remove the terms “enters commerce” and “produced or” from the regulations. It also requested that the Agency adopt a new definition of “shipped.”

FSIS intends to propose regulations that will remove the words “enters commerce” from 417.3(b)(3) and replace them with the words “is produced.” Additionally, the Agency intends to propose that wherever they occur in part 417 the words “produced or shipped” be replaced with the word “produced.” In advance of a regulatory proposal, the Agency is issuing this Notice to clarify the meaning of terms, and to bring maximum consistency to actions taken by inspection program personnel to enforce this requirement.

2. When is product considered produced or shipped for purposes of part 417?

Since the earliest HACCP implementation meetings, FSIS has taken a consistent position on this matter: product is “produced or shipped” under 417 when the establishment completes pre-shipment review as required by 417.5(c). Further, FSIS has consistently indicated that it will be flexible in considering the specific mechanisms that establishments use to meet this requirement (see 63 FR 11104).

This means that pre-shipment review can be accomplished if the product is at a location other than the producing establishment, such as a storage

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location, as long as the review of appropriate documents and compliance with 417.5(c) occurs before the product leaves the control of the producing establishment.

Thus, for purposes of 417 compliance, product may or may not have been physically moved from one location to another to be considered “produced or shipped.” It must, however, have been the subject of a pre-shipment review.

3. What is the purpose of FSIS verification that product has been produced and 417.5(c) requirements met?

Like all FSIS verification activities, this one is designed to ensure that the establishment is meeting the requirements of Part 417. Verifying that the establishment has completed pre-shipment review enables inspection program personnel to know whether the company has taken full and final responsibility for application of its HACCP controls to the product that it has produced and has ensured that the controls have in fact been applied.

4. What should inspection program personnel do to verify 417.5(c) requirements?

Under part 417, inspection program personnel have three general types of verification activities: observation, records review, and product sampling. Verification of pre-shipment review is most frequently accomplished by records review. However, it is advisable to consider performing one verification check by observation, i.e., watching the person perform pre-shipment review, asking questions about what is considered in determining whether to sign-off on a quantity of product, inquiring if the person performing the pre-shipment review is different from the creator of the records, asking whether the person performing pre-shipment review is HACCP-trained, and verifying whose signature on what document shows that pre-shipment review has been completed. Obviously, this can be a complex verification if the establishment uses a sequential approach, or if pre-shipment review is completed after product leaves the production premises. Inspection program personnel may need to phone or e-mail persons at other locations to find out what is done at that location with regard to pre-shipment review. When the verification by observation has been completed, inspection program personnel will be thoroughly familiar with the company's procedures.

After verification that is performed by observation has been successful, records review verification will be appropriate. Records review verification under 417.5(c) should focus on a specific time period and HACCP process; for example, it might focus on the preceding two weeks' 417.5(c) records for production of hot dogs. Records review should consider completeness, i.e., is there a complete set of records showing that pre-shipment review was performed on all the products? If pre-shipment review determinations are based on an establishment employee reviewing other records, is the pre-

shipment review done by someone other than the person who created the records? **Note:** Certain aspects of records review verifications of pre-shipment requirements demand judgment by inspection program personnel before determining there is a non-compliance. If the records review is not being performed by the same person who created the record in a very small establishment, would it be practical to do it another way? If there are several HACCP-trained individuals in the plant, is there a real reason why one individual cannot perform pre-shipment review?

5. What enforcement action should be taken if inspection program personnel determine that there is noncompliance?

Inspection program personnel should consult the Notice on Rules of Practice, (FSIS Notice 36-01) to determine what is the appropriate enforcement action to take. In considering what is appropriate, inspection program personnel must follow Agency policy for prior notification of the establishment.

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